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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,160	11/01/2001	Ronald Alan Coffee	13401	2938
24116	7590	01/11/2006	EXAMINER	
BATTELLE MEMORIAL INSTITUTE 505 KING AVENUE COLUMBUS, OH 43201-2693			OH, SIMON J	
			ART UNIT	PAPER NUMBER
			1618	

DATE MAILED: 01/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/018,160	Applicant(s) COFFEE ET AL.	
	Examiner Simon J. Oh	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-9, 11, 13-16, 18-26, 28-32, 34-48, 51, 52 and 55-70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 18-26, 28, 43, 46-48 and 61-63 is/are allowed.
- 6) ☒ Claim(s) 4-9, 11, 13-16, 29-32, 34-42, 44, 45, 51, 52, 55-60 and 64-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Papers Received

Receipt is acknowledged of the applicant's amendment, response, and petition for extension of time, all received on 06 October 2005. Receipt is acknowledged of the applicant's information disclosure statement, received on 16 August 2005.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 46 and 61-63 under 35 U.S.C. 103(a) as being unpatentable over Coffee is hereby withdrawn.

The rejection of Claims 4-9, 11, 13-16, 29-32, 34-42, 44, 45, 51, 52, 55-60, 64-66 under 35 U.S.C. 103(a) as being unpatentable over Coffee is maintained.

Claims 67-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coffee.

The Coffee document discloses processes and apparatuses for forming material by electrohydrodynamic comminution (See Abstract; and Page 4, Lines 1-4). In one aspect, the processes and apparatuses disclosed within the document is capable of producing various solid and partially solid forms, such as fibers, fiber segments, fibrils, droplets, particles, webs, and mats. This formed matter may also contain a biologically active ingredient (See Page 2, Line 12 to Page 3, Line 15). Fibers, fiber fragments, and particles of biological material, such as fibrin or

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collagen may also be formed using the processes and apparatuses (See Page 6, Lines 13-18). Alternatively, the active ingredient may be provided as a coating or core of the fibers, fibrils, or particles (See Page 5, Lines 7-28). Active ingredients may be supplied onto fibers, fibrils, or droplets in the form of a liquid that is dispensed through an outlet nozzle (See Page 22, Lines 23-33). The reference discloses that fibers have been successfully spun with polyhydroxybutyric acid, a resorbable polymer, and with polyvinyl alcohol, a water-soluble polymer (See Page 19, Lines 20-23). In the formation of material provided by the methods and apparatuses disclosed in the reference, the supply of the material may be assisted by an air or inert gas flow (See Claim 32; and Page 30, Lines 27-31). When a melt is used as the material to be formed by the apparatuses and processes disclosed in the reference, the temperature of this material may be controlled by quenching using a cold air or inert gas stream (See Page 11, Lines 17-22).

The Roche *et al.* patent is used here merely as a teaching reference to show that additives such as saccharin and peppermint flavoring are commonly known in the pharmaceutical arts (See Column 8, Lines 31-58).

As explained above, the Roche *et al.* patent is relied upon merely as a teaching reference. It is the position of the examiner that one of ordinary skill in the art could combine the collective disclosures of the prior art with a reasonable expectation of success. Though the prior art is silent with respect to a cutting step in the disclosed method of production, as the prior art has disclosed the manufacture of particles in addition to fibers and mats, it is the view of the examiner that the use of a cutting step would be within the level of skill of one of ordinary skill in the art. It is also the position of the examiner that the selection of fish gelatin over gelatin of other sources is not a patentable distinction, as the selection of a particular type of gelatin is

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considered to be well within the purview of one of ordinary skill in the art, absent a showing of unexpected results by the applicant. Claim limitations containing specific amounts of specific ingredients are considered by the examiner to be attainable by one of ordinary skill in the art through routine experimentation, and as such as not considered to impart a patentable distinction above the prior art, without a showing of unexpected results. Claim limitations reciting specific moist tissue surfaces are considered by the examiner to be recitations of intended use, and thus do not carry patentable weight.

Thus, the instantly claimed invention is *prima facie* obvious.

Response to Arguments

Applicant's arguments filed 06 October 2005 have been fully considered but they are not persuasive.

It is the position of the examiner that any statement of intended use, whether it is found in the preamble or any other part of a claim, does not render patentability unto that claim, unless it necessarily results in a physical or structural difference that is not obvious in view of the prior art. In the present case, the instantly claimed invention is drawn to solid forms manufactured by electrohydrodynamic comminution comprising an active agent and gelatin. The same is broadly disclosed by the prior art. Therefore, it is assumed that the instantly claimed invention and the prior art both share the property of being able to melt, liquefy, disintegrate or dissolve on specific moist tissue surfaces. The mere recitation of this property or future intended use does not, on its own, add anything further to the instantly claimed invention in terms of physical structure of the instantly claimed or recited compositions, nor does it add anything further to the instantly

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claimed invention in terms of specific ingredients in specific quantities that impart the recited function that would have been unobvious in view of the prior art. Therefore, the art rejection of record will be maintained.

As pointed out by the applicant, Claims 46 and 61-63 depend from the allowed claims. Therefore, the prior art rejection of record will be withdrawn from these claims.

Allowable Subject Matter

Claims 18-26, 28, 43, 46-48 and 61-63 are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Correspondence

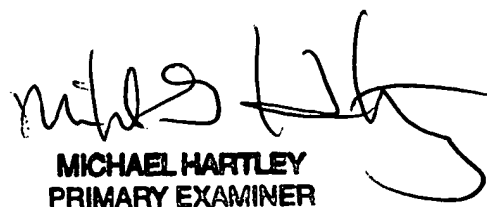
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (571) 272-0599. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Simon J. Oh
Examiner
Art Unit 1618

sj0


MICHAEL HARTLEY
PRIMARY EXAMINER